About the Research Team

Mark H. Greene, M.D., Chief of the NCI Clinical Genetics Branch, is an oncologist and cancer geneticist. He has been caring for and studying patients with familial and hereditary cancers for 25 years.

Sheila Prindiville, M.D., M.P.H., is a medical oncologist and the study's Principal Investigator. She has a special interest in familial breast and ovarian cancer.

Jennifer Loud, M.S.N., C.R.N.P., is a cancer genetics research nurse and oncology nurse practitioner. She coordinates nursing research and care for women in the study.

June Peters, M.S., and **Ann Garrity Carr, M.S.**, genetic counselors, offer group and individual genetic counseling and education services. Ms. Peters conducts research on genetic counseling, family support and communications.

Nancy Weissman, M.S.S.W., is a licensed clinical social worker. She provides support and conducts research on the challenges of coping with high-risk of cancer.

For More Information

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Clinical Genetics Branch

"Saving lives by conquering cancer through research in clinical cancer genetics."

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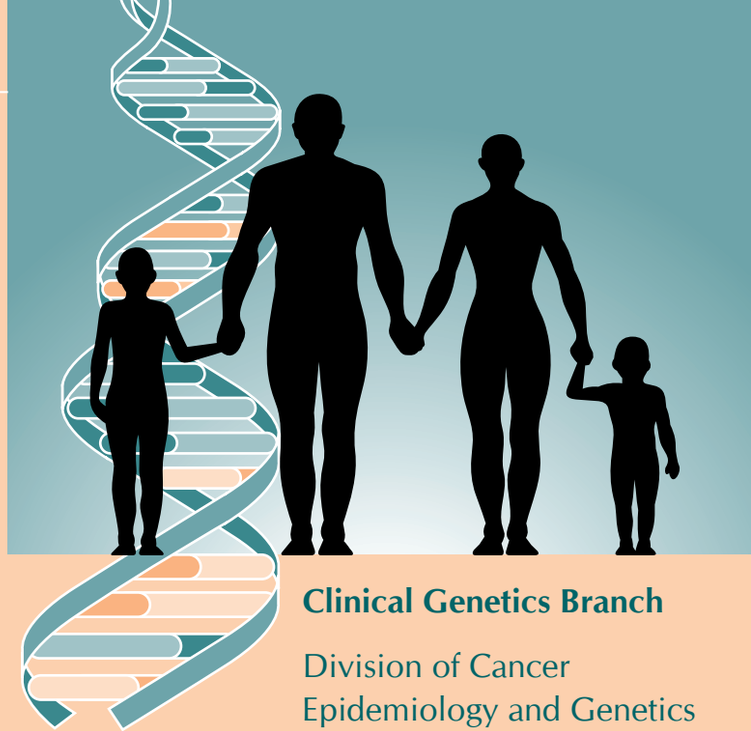

Clinical Genetics Branch

Division of Cancer Epidemiology and Genetics

Women at High Genetic Risk of Breast Cancer

A Breast Imaging Study

Studying methods for early detection of breast and ovarian cancer in genetically high-risk women

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health • **National Cancer Institute**

Purpose

The National Cancer Institute (NCI) is studying women who have a mutation in either of the **BR**east **CA**ncer (**BRCA**) genes, BRCA1 or BRCA2. A mutation in either of these genes places women at much higher risk of early-onset breast and ovarian cancer.

If you are a woman between 25 and 56 years of age, **and** if you know that you have a mutation in either the BRCA1 or BRCA2 gene, NCI invites you to join the study. We hope to learn more about how to find early breast cancers in women with these genetic mutations.

The study's purpose is to:

- Evaluate the newest breast screening procedures to see if they are effective in finding cancer early, especially in younger women
- Develop new tools to find changes in breast cells before cancer occurs
- Examine how women live and cope with a high genetic risk of cancer

Who Is Eligible?

A woman may be eligible to participate if she:

- Is between the ages of 25 and 56
- Has a mutation in either the BRCA1 or BRCA2 gene
- Has received genetic counseling

Women who meet the above criteria and are living with breast cancer may also be eligible, if they have one breast which has not been affected by cancer.

Participating in Research

Those who join the study will be asked to:

- Give a blood sample
- Complete questionnaires about cancer risks and medical history
- Meet with our research clinicians, genetic counselor and social worker

Participants will receive breast and ovarian cancer screening tests at the NIH Clinical Center in Bethesda, Maryland.

Types of Screening

In addition to providing a blood sample and medical information, women will receive:

- A mammogram
- A breast and pelvic examination
- Instruction regarding how to do a breast self-examination
- Ovarian cancer screening with the CA 125 blood test and transvaginal ultrasound of the ovaries
- Sampling of breast milk duct cells (the majority of breast cancer starts in these cells) – procedures used will include either ***Breast Duct Lavage***, where cells are washed from the breast milk ducts, or ***Needle Biopsy***
- Magnetic Resonance Imaging (MRI) of the breast – this uses a strong magnetic field instead of x-rays to create a picture of the breast tissue and may give a clearer view in young women, without exposing them to radiation
- Positron Emission Tomography (PET) scan – this will be done only in women whose mammogram or MRI findings need additional evaluation

Access to our Study Team

Participants will have yearly follow-up visits for four years and are encouraged to stay in touch with the research team between visits.

If follow-up studies are required, our research team will do them at the NIH at no cost to you or your insurance company.

Other Details

Confidentiality. Under Federal law, NCI cannot reveal any information that is collected from study participants to anyone other than persons directly involved with the study. No personal identifying information will be released or published. Access to your personal records is not allowed without your written consent.

Costs. All study-related medical expenses and travel costs to the NIH Clinical Center for participants are paid by NCI.

Treatment. Although treatment is not part of this study, treatment options will be discussed with participants. NCI will also provide assistance in establishing care with appropriate physicians as needed. Study participants will remain under the care of their primary doctors while participating in the study.